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EXAMINER	
PROCTOR, JASON SCOTT	

ART UNIT	PAPER NUMBER
2123	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,725	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Jason Proctor	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42,54-98 and 112-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42,54-98 and 112-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/3/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants are notified that the Examiner of record in this application has been changed.

Claims 1-42, 54-98, and 112-123 are pending in this application.

Response to Interview

Applicants' response 8 June 2005 makes reference to a telephonic interview on 24 January 2005. The current Examiner of record has found no other evidence of this interview in the official record for this application and, as a result, is unaware of any discussion or agreement stemming from that interview.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3 February 2005 was filed after the mailing date of the first Office Action on 24 August 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The previous rejections under 35 U.S.C. § 112, second paragraph, of claims 31 and 41 have been withdrawn.

1. Claims 8-13, 15, 23-28, 30, 36-40, 42, 61-66, 69, 77-82, 85, 91-95, and 98 contain the trademark/trade name TRUEGRID, MIMICS, DYNA3D, NIKE3D or GRIZ. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 1 12, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982).

In response, Applicants' argue primarily that:

> Applicants note that per MPEP 608.01(v) trademarks are permissible in patent applications if the "product to which the trademark refers is set forth in such language that its identity is clear." Applicants submit that the specification clearly identifies the claimed product and provides a clear and definite meaning to the claim terms. *See* FIGS. 5A-8L and page 11, line 8 to page 32, line 18 for a description of TRUEGRID, MIMICS, DYNA3D, NIKE3D, and GRIZ.

The Examiner respectfully traverses this argument as follows.

> MPEP 608.01(v) expressly instructs why the use of trademarks is to be scrutinized:
>
> > The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931).

The trademarked products at issue (TRUEGRID, MIMICS, DYNA3D, NIKE3D, and GRIZ) are computer software. It is generally regarded as a matter of fact that computer software undergoes revisions, updates, and improvements over time. The naming conventions for computer software are the whimsy of software authors. Therefore, the relationship between two different versions of computer software may be little more than a similar title, while the differences may be immense. It remains unknown and indefinite which versions of these trademarked products are referred to by Applicants' claims. The current claim language defines the claimed invention

wherein, using claim 8 as an example, "said geometry generator is (whatever version of) MIMICS (exists in the year 2006)," although the invention was made no later than the year 2000.

Applicants' response makes reference to no fewer than 33 drawing sheets and 21 pages of specification, which comprise more than half of the patent application. This response is insufficient to overcome the basis of the rejection. Applicants' are respectfully encouraged to cite specific portions of the application which will resolve which versions of these trademarked software products are contemplated by the invention, else amend the claim language to avoid the ambiguous use of trademarks.

Applicants' arguments have been fully considered but have been found unpersuasive.

2. Claims 12-13, 27-28, 39-40, 65-66, 81-82, and 94-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite equations that render it impossible to determine the metes and bounds of the claimed invention. Referring to claims 12 and 13 as representative of the others, the parameters "a_{ij}" with various subscripts are vaguely defined as "material parameters". The claims fail to provide a meaningful definition for these parameters such that the claimed invention can be compared against the prior art. There are infinitely many equivalent statements for mathematical equations, and therefore the novelty of a particular equation can only be determined when that equation is clearly defined. In this instance, the "material parameters" could define an equation in terms of weight, color, density, mass, temperature, stiffness, dimension, shape, internal stress, or others. It is impossible to determine how these equations are

actually defined and therefore impossible to determine the metes and bounds of the claims which recite them.

As these claims attempt to modify DYNA3D and NIKE3D, these claims will be interpreted as equivalent to the equations inherent in DYNA3D and NIKE3D.

Claim Objections

3. Claim 120 is objected to because it is unclear how the recited limitation further defines the method of the parent claim. In particular, the phrase "a geometric model of an *in vitro* failure mode test" is unclear and interpreted to mean "a geometric model for use in an *in vitro* failure mode test." As understood by the Examiner as known in the art, a "failure mode test," especially in the context of finite element analysis, is a process and therefore not adequately represented by "a geometric model."

Claim 121 highlights the observation that a "failure mode test" is a process by reciting "simulating comprises simulating ... in said *in vitro* failure mode test." Although not recited, by way of example, it would similarly be unknown what is meant by "a geometric model of a simulation or any other process," especially in the context of the claims.

Appropriate correction is required.

Claim Rejections - 35 USC §§ 102 & 103

The previous rejections under 35 U.S.C. §§ 102 & 103 have been withdrawn in response to Applicants' arguments, which have been fully considered and found persuasive at least in part.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 16-18, 31, 32, 54, 56, 70, 72, 86, 113, 115, 117, 118, and 119, rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,594,651 to St. Ville.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, St. Ville discloses a system for analyzing medical devices (abstract; column 16, lines 37-58) comprising:

A geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry ... is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below."* (column 9, lines 31-38)];

A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh based on both of said geometric model of said anatomical features and said geometric model of said medical device [*"A finite element model is again created, but now includes another layer,*

namely, the artificial hip embedded in the cancellous bone area." (column 17, lines 4-6); FIGS. 4A, 4B]; and

A stress/strain/deformation analyzer that receives said finite element model or mesh materials properties of said anatomical features and said medical device, load data on said anatomical features, and/or said medical device, and simulates an interaction between said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*"a finite element analysis may be performed using the fine mesh model of FIG. 6 which includes 5207 nodes and 5040 isoparametric solid elements."* (column 17, lines 4-9); FIG. 6 depicts an anatomical feature (bone structure) and medical device (prosthetic hip join). *"In the case of the prosthetic hip, the defined potentials are the desired displacements (which correlate mathematically to the stresses) in the prosthetic hip when the prosthetic hip is subjected to the mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 26-30)].

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville discloses that the geometric model of said anatomical features is an idealized geometric model [*"First, a finite element model of the normal*

bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals..." (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 113, 115, 117, 118, and 119, St. Ville discloses that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [*"mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

5. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure."* (column 7, lines 8-14)].

St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of St. Ville because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

6. Claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher (Whitcher, provided by Applicants via PTO-1449 submitted on 3 February 2005).

St. Ville does not expressly teach that the medical device as an endovascular prosthesis, a stent graft, or a cardiovascular stent.

Whitcher teaches finite element simulation analysis of "vascular support structures (stents and grafts) to provide designers with estimates of their in-vivo structural behavior and fatigue properties" (abstract).

St. Ville and Whitcher are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the analysis of cardiovascular stents and grafts as taught by Whitcher with the modeling system of St. Ville because Whitcher expressly teaches that "there is a high priority to deliver high performance vascular stents to the health care practitioner" (page 607, "Introduction") and Whitcher's method provides "simulation analysis of vascular support structures (stents and grafts), to provide designers with estimates of their in-vivo structural behavior and failure properties" (abstract), thereby providing a solution that makes it easier to design and provide successful vascular stents to the health care practitioner.

Claims 20-22, 33-35, 58-60, 74-76, and 88-90 reiterate the limitations of claims 5-7 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 5-7.

7. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

St. Ville does not expressly disclose using MIMICS as a geometry generator.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

St. Ville and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of St. Ville because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

8. Claims 9, 24, 36, 62, 78, and 91 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "Finite Element Analysis of Human Joints" by P-L. Bossart and K. Hollerbach (Hollerbach, provided by Applicants via PTO-1449 submitted on 21 February 2002).

St. Ville does not expressly disclose that the mesh generator is TRUEGRID.

Hollerbach teaches methods of developing finite element models that describe the biomechanics of human joints (abstract). Hollerbach teaches using the "TrueGrid ... meshing package" (page 2, left column, "Volumetric mesh generation and finite element modeling").

St. Ville and Hollerbach are analogous art because both are directed to finite element modeling.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use the TrueGrid meshing package taught by Hollerbach in the modeling system of St. Ville because Hollerbach expressly teaches how to "create accurate

FEMs of human joints from 3D X-ray CT data sets and to minimize the amount of human interaction required" (page 2, right column, "Conclusion") and therefore at least enhances the accuracy of the finite element models.

Claims 24, 36, 62, 78, and 91 reiterate the limitations of claim 9 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 9.

9. Claims 10-13, 25-28, 37-40, 63-67, 79-83, 92-96, 112, 114, and 116 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claims 10-11, St. Ville does not expressly disclose that the stress/strain/deformation analyzer is DYNA3D or NIKE3D.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

St. Ville and Raboin are analogous art because both are directed to modeling of prosthetic joints.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the

modeling system of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 25-26, 37-38, 63-64, 79-80, and 92-93 reiterate the limitations of claims 10-11 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 10-11.

Claims 12-13, 27-28, 39-40, 65-66, 81-82, and 94-95 have been interpreted as set forth above and are therefore rejected for rationale similar to that given above for claims 10-11.

Regarding claim 112, St. Ville does not expressly disclose that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool.

Raboin teaches that NIKE3D is a "Nonlinear, three-dimensional, finite-element modeling" tool (page 6 of 13, "NIKE3D for Biomechanics"). Therefore, claim 112 is rejected rationale similar to that given above for claim 11.

Claims 67, 83, 96, 114, and 116 reiterate the limitations of claim 112 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 112.

10. Claims 14-15, 29-30, 41-42, 68-69, 84-85, and 97-98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey).

St. Ville does not expressly disclose the use of GRIZ as a visualization tool that displays one or more of said stresses, strains, and deformations of said medical device via visual representation.

Dovey teaches that GRIZ is "a general-purpose post-processing application supporting interactive visualization of finite element analysis results on unstructured grids. GRIZ calculates and displays derived variables for a variety of analysis codes. Currently, GRIZ works with the family of Methods Development Group (MDG) analysis codes, including DYNA3D, NIKE3D, and TOPAZ3D." (page 1, "Introduction"). Dovey teaches that GRIZ displays the results of various parameters (page 21, "Results Command"), including various stress results variables (*ex.* "sx", page 21); strain variables (*ex.* "ex", page 22); and deformation (*ex.* "dispx", page 24).

St. Ville and Dovey are analogous art because both are directed toward finite element analysis.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use GRIZ as taught by Dovey to visualize the results of the modeling system of St. Ville because Dovey expressly teaches that "GRIZ provides flexible control of mesh materials on an individual basis, allowing the user to concentrate analysis and visual focus on important subsets of the mesh. GRIZ incorporates the ability to animate all representations over time," thereby enhancing the analysis capabilities present in the system taught by St. Ville to increase productivity.

Claims 29-30, 41-42, 68-69, 84-85, and 97-98 reiterate the limitations of claims 14-15 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 14-15.

11. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles... Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed..."* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and

structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate... This result corresponds more closely to the fractographic findings* [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations..."* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the* in vitro *data were simply evaluated..."* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached at (571) 272-3749. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Proctor
Examiner
Art Unit 2123

jsp

Paul L. Rodriguez 2/2/06
Primary Examiner
Art Unit 2125